

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

ROBERT J. PEACH ET AL.

PATENT NO: 7,094,874

ISSUED: AUGUST 22, 2006

FOR: SOLUBLE CTLA4 MUTANT MOLECULES AND USES THEREOF

FILING VIA EFS-WEB

Mail Stop: PETITIONS

Director, U.S. Patent & Trademark Office

P.O. Box 1450

Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

Sir:

This is a request for further reconsideration of patent term adjustment on U.S. patent No. 7,094,874. The Office of Petitions recently determined that the patent term adjustment should be 261 days. However, in view of recent legal developments and as explained below, the patent term adjustment should be 696 days.

The Patent Office Applied an Improper Method of Calculating PTA

The U.S. District Court for the District of Columbia recently held that the Patent Office has been applying an improper method of calculating patent term adjustment.

Wyeth v. Dudas, 2008 WL 4445642 (D.D.C. September 30, 2008). The Patent Office applied that improper method in the present case, resulting in a 435 day error.

The statute governing patent term adjustment, 35 U.S.C. § 154(b), defines certain periods of Patent Office delay that give rise to extensions of patent term. These include an "A period" concerning Patent Office failure to comply with certain deadlines (defined by 35 U.S.C. § 1.54(b)(1)(A)) and a "B period" concerning Patent Office failure to issue a patent within 3 years after the actual filing date of a patent application (defined by 35 U.S.C. § 1.54(b)(1)(B)).

In *Wyeth*, the Patent Office argued that any administrative delay under the A period overlaps any 3-year maximum pendency delay under the B period, such that delays should be credited to the A period or B period, but not to both periods. The court rejected that argument. It held that delays may be credited to both the A period and B period, except to the extent those periods overlap by occurring on the same calendar days.

In view of *Wyeth*, Petitioners request reconsideration of the patent term adjustment for the subject patent.

Calculation of the B Period

The patent term adjustment history from PAIR (attached as Appendix A) shows an adjustment of 84 days for the B period. However, the B period should be 519 days.

Relevant dates for calculating the B period are listed below.

Application Filing Date: May 23, 2001

3-year Anniversary of Filing: May 23, 2004

Request for Continued Examination: October 24, 2005

Patent Issue Date: August 22, 2006

The patent issue date was 821 days after the 3-year anniversary of the filing date. However, time consumed by examination after a request for continued examination does not count toward the B period. In this case, 302 days elapsed from the filing of a request for continued examination until the patent issued. So the B period is calculated as follows: 821 days - 302 days = 519 days. That is a difference of 435 days when compared with the Patent Office's improper 84 day calculation.

The Director Should Add 435 More Days to the Patent Term Adjustment

Considering the corrected B period, the Director should add 435 more days to the patent term adjustment. The B period delays did not occur on the same calendar days as the A period delays. In particular, the 519 day B period delay (beginning May 23, 2004 on the three-year anniversary of the filing date and ending October 24, 2005 on the filing of a request for continued examination) did not overlap with either the 435 day delay (ending

October 1, 2003 on the mailing of a restriction requirement) or the 24 day delay (ending August 22, 2006 on issuance of the patent)¹ that constitute the A period.

Accordingly, Petitioners request 435 more days of patent term adjustment, bringing the total patent term adjustment to 696 days ($261 + 435 = 696$). The patent is not subject to any terminal disclaimer that would impact such a correction.

Timeliness of this Request

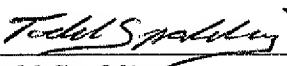
This request is being filed within two months of a decision by the Office of Petitions (attached as Appendix B) concerning patent term adjustment on the subject patent. Petitioners acknowledge that the request does not respond to any point made in that decision and that it is being filed more than two months after issuance of the patent. However, Petitioners timely raised the patent term adjustment issue in a previous paper and have promptly filed this further request after (a) the recent decision by the Office of Petitions and (b) the *Wyeth* decision. The specific arguments made in this request could not have been made earlier. Accordingly, the request is timely.

Payment of Any Required Fees

If any fees are required for consideration of this request, please charge them to Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

Respectfully submitted,

Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000
Tel. No. (609) 252-3034



Todd Spalding
Attorney for Applicants
Reg. No. 55,638

Date: November 21, 2008

¹ Petitioners note that the 24 day delay occurred more than three years after the application was filed but after the filing of a request for continued examination. Because time after a request for reconsideration does not count toward the B period (even though it is beyond the three year date), there is no overlap of calendar days.

**Appendix A -
Patent Term Adjustment History for
U.S. Patent No. 7,094,874 (U.S. Patent Application No. 09/865,321)**

09/865,321

SOLUBLE CTLA4 MUTANT MOLECULES AND USES THEREOF

11-19-

2008::15:16:02

Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 09/865,321

| | | | |
|------------------------------|------------|--------------------------------------|-----|
| Filing or 371(c) Date: | 05-23-2001 | USPTO Delay (PTO) Delay (days): | 543 |
| Issue Date of Patent: | 08-22-2006 | Three Years: | - |
| Pre-Issue Petitions (days): | +0 | Applicant Delay (APPL) Delay (days): | 290 |
| Post-Issue Petitions (days): | +0 | Total PTA (days): | 261 |
| USPTO Adjustment(days): | 8 | Explanation Of Calculations | |

Patent Term Adjustment History

| Date | Contents Description | PTO(Days) | APPL(Days) |
|------------|---|-----------|------------|
| 09-30-2008 | Record a Petition Decision of Granted for Patent Term Adjustment after Issue | | |
| 09-26-2007 | Adjustment of PTA Calculation by PTO | 81 | |
| 02-21-2007 | Mail-Record a Petition Decision of Granted for Patent Term Adjustment after Issue | ↑ | |
| 02-20-2007 | Adjustment of PTA Calculation by PTO | | 81 |
| 02-20-2007 | Adjustment of PTA Calculation by PTO | 8 | |
| 08-02-2006 | PTA 36 Months | 84 | |
| 08-22-2006 | Patent Issue Date Used in PTA Calculation | 24 | |
| 07-12-2006 | Dispatch to FDC | ↑ | |
| 06-09-2006 | Workflow - Drawings Finished | | 75 |
| 06-01-2006 | Miscellaneous Communication to Applicant - No Action Count | | ↑ |
| 05-31-2006 | Sequence Forwarded to Pubs on Tape | | ↑ |
| 05-11-2006 | Workflow - Drawings Finished | | 29 |
| 04-27-2006 | Mail Examiner Interview Summary (PTOL - 413) | | ↑ |
| 04-27-2006 | Mail Miscellaneous Communication to Applicant | | ↑ |
| 04-26-2006 | Miscellaneous Communication to Applicant - No Action Count | | |
| 04-19-2006 | Examiner Interview Summary Record (PTOL - 413) | | |
| 04-20-2006 | TC Return to Pubs | | |
| 04-20-2006 | Miscellaneous Incoming Letter | | 8 |
| 04-08-2006 | Pubs Case Remand to TC | | |
| 04-05-2006 | Application Is Considered Ready for Issue | | |
| 04-04-2006 | Correspondence Address Change | | |
| 03-29-2006 | Issue Fee Payment Verified | | |
| 03-29-2006 | Issue Fee Payment Received | | |
| 03-29-2006 | Sequence Forwarded to Pubs on Tape | | |
| 03-21-2006 | Mail Notice of Allowance | | |
| 03-13-2006 | Notice of Allowance Data Verification Completed | | |
| 01-13-2006 | Information Disclosure Statement considered | | |
| 01-23-2006 | Information Disclosure Statement considered | | |

| | | | |
|------------|--|--|----|
| 01-13-2006 | Information Disclosure Statement considered | | |
| 12-05-2005 | Information Disclosure Statement considered | | |
| 10-24-2005 | Information Disclosure Statement considered | | |
| 01-13-2006 | Information Disclosure Statement (IDS) Filed | | |
| 01-23-2006 | Information Disclosure Statement (IDS) Filed | | 10 |
| 02-01-2006 | Date Forwarded to Examiner | | ↑ |
| 01-13-2006 | Response after Non-Final Action | | ↑ |
| 01-13-2006 | Request for Extension of Time - Granted | | |
| 01-13-2006 | Information Disclosure Statement (IDS) Filed | | |
| 01-19-2006 | IFW TSS Processing by Tech Center Complete | | |
| 12-05-2005 | Reference capture on IDS | | |
| 12-05-2005 | Information Disclosure Statement (IDS) Filed | | |
| 11-14-2005 | Mail Notice of Informal or Non-Responsive RCE Amendment | | |
| 11-10-2005 | Notice of Informal or Non-Responsive RCE Amendment. | | |
| 10-24-2005 | Information Disclosure Statement (IDS) Filed | | |
| 11-10-2005 | Date Forwarded to Examiner | | |
| 11-10-2005 | Date Forwarded to Examiner | | |
| 10-24-2005 | Request for Continued Examination (RCE) | | |
| 11-10-2005 | DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA) | | |
| 10-24-2005 | Request for Extension of Time - Granted | | |
| 10-24-2005 | Workflow - Request for RCE - Begin | | |
| 03-24-2005 | Notice of Appeal Filed | | 87 |
| 03-24-2005 | Request for Extension of Time - Granted | | ↑ |
| 01-10-2005 | Mail Advisory Action (PTOL - 303) | | ↑ |
| 01-06-2005 | Advisory Action (PTOL-303) | | ↑ |
| 12-10-2004 | Date Forwarded to Examiner | | ↑ |
| 11-29-2004 | Amendment after Final Rejection | | ↑ |
| 12-08-2004 | Correspondence Address Change | | ↑ |
| 11-29-2004 | Workflow incoming amendment IFW | | ↑ |
| 11-29-2004 | Workflow incoming amendment IFW | | ↑ |
| 09-27-2004 | Mail Final Rejection (PTOL - 326) | | ↑ |
| 09-24-2004 | Final Rejection | | |
| 07-24-2004 | Date Forwarded to Examiner | | |
| 07-19-2004 | Response after Non-Final Action | | 42 |
| 07-19-2004 | Workflow incoming amendment IFW | | ↑ |
| 06-18-2004 | Mail Notice of Informal or Non-Responsive Amendment | | ↑ |
| 06-17-2004 | Date Forwarded to Examiner | | ↑ |
| 06-07-2004 | Informal or Non-Responsive Amendment after Examiner Action | | ↑ |
| 06-07-2004 | Response after Non-Final Action | | 39 |

| | | | | | |
|------------|--|--|-----|--|---|
| 06-07-2004 | Request for Extension of Time - Granted | | | | ⬆ |
| 06-07-2004 | Workflow incoming amendment IFW | | | | ⬆ |
| 06-05-2004 | Case Docketed to Examiner in GAU | | | | ⬆ |
| 04-06-2004 | Case Docketed to Examiner in GAU | | | | ⬆ |
| 01-29-2004 | Mail Non-Final Rejection | | | | ⬆ |
| 01-26-2004 | Non-Final Rejection | | | | |
| 11-03-2003 | Miscellaneous Incoming Letter | | | | |
| 11-13-2003 | Date Forwarded to Examiner | | | | |
| 11-03-2003 | Response to Election / Restriction Filed | | | | |
| 10-01-2003 | Mail Restriction Requirement | | 435 | | |
| 09-30-2003 | Requirement for Restriction / Election | | ⬆ | | |
| 01-31-2003 | Case Docketed to Examiner in GAU | | ⬆ | | |
| 01-17-2003 | Application Return from OIPE | | ⬆ | | |
| 01-17-2003 | Application Is Now Complete | | ⬆ | | |
| 11-12-2002 | Additional Application Filing Fees | | ⬆ | | |
| 05-23-2001 | Claim Preliminary Amendment | | ⬆ | | |
| 11-12-2002 | Additional Application Filing Fees | | ⬆ | | |
| 12-26-2002 | Pre-Exam Office Action Withdrawn | | ⬆ | | |
| 12-26-2002 | Application Return TO OIPE | | ⬆ | | |
| 12-26-2002 | Application Return from OIPE | | ⬆ | | |
| 12-24-2002 | Application Is Now Complete | | ⬆ | | |
| 05-23-2001 | Additional Application Filing Fees | | ⬆ | | |
| 05-23-2001 | Claim Preliminary Amendment | | ⬆ | | |
| 05-23-2001 | Translation of Claims into English | | ⬆ | | |
| 05-23-2001 | Claim Preliminary Amendment | | ⬆ | | |
| 11-12-2002 | A set of symbols and procedures, provided to the PTO on a set of computer listings, that describe in | | ⬆ | | |
| 12-13-2002 | CRF Is Good Technically / Entered into Database | | ⬆ | | |
| 10-11-2002 | SEQUENCE ERRORS | | ⬆ | | |
| 08-17-2001 | A set of symbols and procedures, provided to the PTO on a set of computer listings, that describe in | | ⬆ | | |
| 07-02-2002 | Pre-Exam Office Action Withdrawn | | ⬆ | | |
| 10-01-2002 | Application Return TO OIPE | | ⬆ | | |
| 09-17-2002 | Application Made Unavailable for Examination | | ⬆ | | |
| 08-12-2002 | Case Docketed to Examiner in GAU | | ⬆ | | |
| 05-06-2002 | Information Disclosure Statement (IDS) Filed | | ⬆ | | |
| 01-29-2002 | Information Disclosure Statement (IDS) Filed | | ⬆ | | |
| 06-14-2002 | Information Disclosure Statement (IDS) Filed | | ⬆ | | |
| 03-12-2002 | Information Disclosure Statement (IDS) Filed | | ⬆ | | |
| 08-17-2001 | Preliminary Amendment | | ⬆ | | |
| 07-16-2001 | Preliminary Amendment | | ⬆ | | |
| 06-21-2001 | Information Disclosure Statement (IDS) Filed | | ⬆ | | |

| | | |
|------------|---|---|
| 07-03-2002 | Application Dispatched from OIPE | ↑ |
| 07-02-2002 | Application Is Now Complete | ↑ |
| 09-20-2001 | CRF Is Good Technically / Entered into Database | ↑ |
| 06-11-2001 | Notice Mailed--Application Incomplete--Filing Date Assigned | ↑ |
| 06-11-2001 | Correspondence Address Change | ↑ |
| 06-01-2001 | IFW Scan & PACR Auto Security Review | ↑ |
| 05-23-2001 | Initial Exam Team nn | ↑ |

Close Window

Appendix B -

**Decision on Request for Reconsideration of Decision on Request for Reconsideration of
Patent Term Adjustment and Notice of Intent to issue Certificate of Correction**



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

Paper No.

LOUIS J. WILLE
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON NJ 08543-4000

COPY MAILED

OCT 01 2008

OFFICE OF PETITIONS

| | | |
|-----------------------------|---|---------------------------|
| In re Patent No. 7,094,874 | : | DECISION ON REQUEST |
| Peach et al. | : | FOR RECONSIDERATION OF |
| Issue Date: August 22, 2006 | : | DECISION ON |
| Application No. 09/865,321 | : | REQUEST FOR |
| Filed: May 23, 2001 | : | RECONSIDERATION OF |
| Atty Docket No. D0028PNP; | : | PATENT TERM ADJUSTMENT |
| 30436.57USU1 | : | and |
| | : | NOTICE OF INTENT TO ISSUE |
| | : | CERTIFICATE OF CORRECTION |

This is a decision on the "RESPONSE TO DECISION ON SECOND REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT" filed February 29, 2008. Patentees request that the revised Patent Term Adjustment shown on the above captioned patent (and on the Certificate of Correction issued March 27, 2007) be corrected to two hundred sixty-one (261) days.

The second request for reconsideration of the decision of February 21, 2007 is GRANTED.

The patent term adjustment indicated in the patent is to be corrected by issuance of another certificate of correction showing a revised Patent Term Adjustment of two hundred sixty-one (261) days.

On August 22, 2006, the above-identified application matured into U.S. Patent No. 7,094,874 with a revised patent term adjustment of 253 days. By decision mailed February 21, 2007, the request for reconsideration of patent term adjustment filed October 20, 2006 was granted-in-part. By certificate of correction issued March 27, 2007, the patent term adjustment indicated in the patent was corrected to ONE HUNDRED EIGHTY

(180) days. This correction was based in part on entry of a period of reduction of 81 days pursuant to 37 CFR 1.704(c)(7).

The 81-day reduction is at issue. The decision mailed February 21, 2007 entered the reduction on the basis that the response filed October 24, 2005 included an omission as reflected by the mailing of a Notice of Non-compliant Amendment on November 14, 2005. As the further response correcting the omission was filed on January 13, 2006, a period of reduction of 81 days was entered.

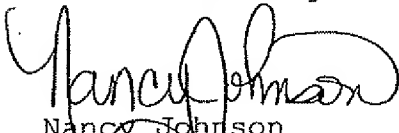
Patentees' arguments as set forth on instant request for reconsideration, in light of the Office's action at the time of filing of the paper on January 13, 2006, has been reconsidered and found persuasive. It is concluded that entry of a period of reduction of 81 days on decision on request for reconsideration of patent term adjustment was not warranted.

Accordingly, the decision on application for patent term adjustment has been reconsidered and the reinstatement of 81 days of patent term is granted.

The \$200.00 fee set forth in 37 CFR 1.18(e) was submitted on request for reconsideration of patent term adjustment filed October 20, 2006. No additional fees are required.

The application file is being forwarded to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify this error. The Office will issue another certificate of correction indicating that the term of the above-identified patent is extended or adjusted by two hundred sixty-one (261) days.

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-3219.



Nancy Johnson
Senior Petitions Attorney
Office of Petitions

Enclosure: Copy of DRAFT Certificate of Correction

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT : 7,094,874 B2

DATED : August 22, 2006

DRAFT

INVENTOR(S) : Peach et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by 253 days

Delete the phrase "by 253 days" and insert -- by 261 days--